Exhibit H

Establishment Inspection Report	FEI:	**3003999190**
Zhejiang Huahai Pharmaceutical Co., Ltd.	EI Start:	08/05/2013
Linhai, China	EI End:	08/09/2013

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Paroxtine IR	Anti-depression	[redacted]
Ropinirole ER	Parkinson	[redacted]
Valsartan	Hypertension	[redacted]
Losartan-HCTZ	Hypertension	[redacted]
Aripiprazole	Antipsychotic	[redacted]
Fosinopril	Hypertension	[redacted]
Quinapril	Hypertension	[redacted]
Valsartan-HCTZ	Hypertension	[redacted]
Escitalopram	Anti-depression	[redacted]
Donepezil ODT	Alzheimer	[redacted]

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

We presented our credentials to Mr. Baohua Chen, President, who is the most responsible person for the site, at the initiation of the inspection. Mr. Chen and his management staff provided a brief overview of the firm's history and current operations. The firm's current organizational chart is included in **Exhibit 2**. The primary contacts during the inspection were Jun Du, Executive VP, CunXiao Ye, Vice General Manager, QA, Hai Wang, Senior VP- Business Development and Sales (Huahai US), and Lihong (Linda) Lin, Assistant General Manager-API RA. They facilitated the inspection by arranging inspections of the warehouse, manufacturing, and laboratory areas, answering questions, making the employees available and providing documentation.

The following managers were present during the opening and closing meetings:
Baohua Chen, President
Jun Du, Executive Vice President
CunXiao (Jenson) Ye, Vice General Manager, Quality Assurance (Qualified Person)
Hai Wang, Senior Vice President, Business Development & Sales (Huahai US Inc.)
Qimao Chen, Vice President, Pharmaceuticals Manufacture
Chunmin Xu, Vice General Manager, API Manufacture EHS
Lihong (Linda) Lin, Assistant General Manager, API Regulatory Affairs
Jie Wang, Vice President, Business Development
Min Da Cai, Vice President, Marketing & Sales
Jianguo An, Director, API Manufacture Quality Control
Xiaodi Guo, Vice President, Huahai Institute of Pharmaceutical Research
Pieter Groenewoud, Executive Director of Technology, Pharmaceuticals Manufacture
Yanhua (Anne) Meng, Plant Director, API Manufacturing (Xunqiao site)
Juan Tao, Manager, Pharmaceuticals Manufacture Quality Assurance

The firm has a defined Quality unit managed by Mr. Ye who reports directly to Mr. Baohua Chen on quality issues. The creation, approval, and maintenance of required records at all sites for both products categories (API and FDF) are defined by Standard Management Procedures (SMP) at the corporate level. Operating procedures for specific sites and product types are governed by Standard Operation Procedures (SOP). For Xunqiao operations, the Quality Department has 6 (QA) personnel at the corporate level, 87 (16 QA, 71 QC) covering API and 82 (20 QA and 62 QC) covering FDF. The Quality unit manages the entire supply chain from raw materials, supplier qualification, QC testing, validation, QA release to finish product. QA is responsible for approving and maintaining records and written procedures regarding the production, control, and distribution of API and FDF products.

Annual Product Reviews

(MCB) I reviewed the firm's annual product reviews (APR) for Captopril API and Benazepril API and tablets for 2012. The annual product reviews, as defined in the SMP-020.02 "Annual Product Review Management System", covered the batches manufactured during the period and were completed in a timely manner. The reviews covered deviations, OOS, complaints, rejects, change control, validation, and process improvements. It also trended the values obtained for yields, testing results, and stability. I did not note any discrepancies in the annual product reviews.

Deviations

(CS) I reviewed the firm's SMP-017.02 entitled, "Deviation Investigation Management System", effective 4/15/13. For OOS/OOT investigations, they are covered under a different SMP. The deviations are classified as either minor or major (when potentially affecting product quality), and the number is assigned by QA chronologically after an initial assessment based on the date of report as DX-YYZZZ. X is site code with A stands for Xunqiao API site and F for Xunqiao FDF site. YY is the reporting year. When the deviation is related to validation activities, a prefix "R" would be added to the code. During the investigation, the firm may initiate intermediate action to limit potential problem. After root cause is identified and the firm would implement correction actions before closeout. The firm provided me for further review with a list of deviations for all FDF and API products manufactured at Xunqiao from 2011 to 2013 (up to DF-13014, dated 6/9/2013). All the reports have been properly investigated and closed. Because Fosinopril Sodium USP was not included in the list of commercial API destined for the US when we made the request, only the deviations for 5 other APIs were included (see API list on page 6). The following deviation is noted below.

DF-12025 was initiated on 5/2/2012 after packaging Donepezil Hydrochloride tablets (batch # 210B12008). Ms. Juan Tao stated that the deviation resulted from the findings when the operator counted bottle labels (Huahai batch 7299-12-001, and supplier's batch 10619) and found the total labels reconcillation was 101.64% instead of 100% during label reconciliation. An initial investigation suggested that the supplier provided additional labels without informing Huahai. In addition, Huahai realized that there was no requirement to count the labels before use in the current version of SOPL1-020-6, Standard Operation Procedure for Secondary Packaging Process. The firm

4) Conclusions in investigations are not always clear, especially in customer complaint investigations. For investigations where the issue is not likely to have happened here, do not state that as a conclusion.

5) API raw material supplier OOSs do not include a follow up to say if the requested investigation was performed by the supplier and what the outcome was.

6) The excursion for labeling reconciliation was thoroughly investigated and corrected. The root cause was because there was no verification by QA of the quantity of labels when received and released. I pointed out that Huahai should not solely rely upon supplier for the accurate counts. QA or packaging line operators should also count the remaining labels when returning them to QA.

7) The purified water systems at Xunqiao site actually could be differentiated into one with hot recirculation loop (FDF Workshop V), one with heat exchanger to facilitate high temperature (80 C) sanitization when needed (API Workshop VIII or FDF Workshop IV), and the others with ambient (cold) loops. I discussed with the firm about the potential for biofilm growth and the need to closely monitor the systems.

Baohua Chen, President, promised to correct/evaluate all discussion items and to expand the corrections to any related issues.

ADDITIONAL INFORMATION

Accommodations

(MBC) Lodging for the trip was at the S&N international Hotel in Linhai. The hotel is about 15 minutes from the firm, and is satisfactory. Transportation to and from the firm was by provided by the firm.

It should be noted that the Xunqiao site consists of both a fairly large API plant and a fairly large finished dosage plant, both of which have several products for the U.S. market and are adding more. Adequate inspectional coverage of this site is difficult to achieve in one week, since the API and finished dosage plants have many differences in operations and procedures, and only share common management at the highest level of the organization. The site should be assigned for foreign trip planning as though it were two inspections, even if the site retains only one FEI.

SAMPLES COLLECTED

There were no samples collected during the inspection.